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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,121	11/27/2000	Gautam Khurana	07039-296001	5932

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EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1633	6

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/723,121	KHURANA ET AL.	
	Examiner	Art Unit	
	Celine Qian	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-29 are pending in the application.

Claim Objections

Claim 28 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim references to two sets of claims to different features. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9, 19, 20 and 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 6-9, 19 and 20 the word "proximity" renders the claims indefinite because it is not clear how close the lumen opening and the contact surface need to be. Regarding claims 21-29, the phrase "in communication with" renders the claims indefinite because it is not clear how the contact surface should associate with the first end of the lumen, for example, should it be connected or merely two independent part that can be used simultaneously to deliver a pharmaceutical composition? As such, the metes and bounds of the claimed subject cannot be established.

Claim 26 and 29 recite the limitation "said syringe and conduit tubing" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al (WO 99/08713).

Claims 1, 5 and 10 are drawn to a method of delivering a pharmaceutical composition comprising a nucleic acid to a tissue site by providing a gene delivery device a contact surface, applying said pharmaceutical composition to said surface, and contact said surface to said tissue site, wherein said nucleic acid is selected from group consisting of DNA, RNA, anti-sense molecules, triplex-helix forming nucleic acids, aptamers and ribozymes; wherein the tissue is selected from the group including blood vessel, skin, etc.

Tang et al. disclose a vector containing adhesive bandage that can be adhered to skin and deliver said vector to skin cells (see page 24, example 8). Such bandage comprises a contacting surface and a nucleic acid. Tang et al. also disclose a method of deliver the vector comprising a nucleic acid by pipetting the vector to the bandage and adhere the bandage to naked skin of mice. Therefore, Tang et al. disclose the claimed invention.

Claims 4, 6, 11, 14, 17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman (US 5,318,514).

Claim 4 is drawn to a method for delivering a pharmaceutical composition comprising a nucleic acid to a tissues site by applying said composition to the contact surface of a gene

delivery device and contacting said surface to said tissue site, wherein the contact surface can be either a plurality of bristles, a plurality of fibers or a sponge.

Claim 6 is drawn to a method for delivering a pharmaceutical composition comprising a nucleic acid to a tissues site by applying said composition to the contact surface of a gene delivery device and contacting said surface to said tissue site, wherein the gene delivery device further comprises a lumen with an opening close to said contact surface, and wherein said applying comprises delivering said pharmaceutical composition through said opening to the contact surface.

Claims 11 and 14 are drawn to a kit comprising a gene delivery device comprising a contact surface and a pharmaceutical composition comprising a nucleic acid, wherein the nucleic acids can be selected from group consisting of DNA, RNA, anti-sense molecules, triplex-helix forming nucleic acids, aptamers and ribozymes.

In the instance that claim 17 is dependent on claim 11, claim 17 is drawn to a kit according to claim 11, wherein said delivery device further comprising a longitudinal axis and said contact surface is detachable from said graspable element.

In the instance that claim 19 is dependent on claim 11, claim 19 is drawn to a kit according to claim 11, wherein said delivery device further comprising a lumen and having an opening close to said contact surface for delivering pharmaceutical composition to a tissue being contacted with said contact surface.

In the instance that claim 20 is dependent on claim 11, claim 20 is drawn to a kit according to claim 11, where in said delivery device further comprising a double barreled syringe and conduit-tubing.

Hoffeman discloses an apparatus for delivering pharmaceutical compounds and genes into live cells of a patient, wherein said apparatus comprises a contact surface (see Figure 1 and 2, part 16), and said contact surface is a sponge-like substrata (see Figure 2, part 20, page 3, column 2, line 59). Said apparatus also comprises a flexible tube coupled to the contact surface, wherein the other end of the tube is coupled to a fluid medium source (see Figure 1, part 32 and 14), and fluid comprising pharmaceutical composition can be drawn from the medium source and deliver through the opening of the tube to said contact surface (see page 3, column 2, line 53-58). Said apparatus further comprises a handle and an arm with an attachable head (see Figure 1, part 10, 26 and 16). Although, Hoffeman does not specify what is the fluid medium source, it is reasonable to suggest that a double barreled syringe is within the spectrum of his disclosure. Therefore, Hoffeman discloses the instant claimed inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (US 5,318,514).

Claim 12 is drawn to a kit comprising a gene delivery device and pharmaceutical composition comprising a dye or other detectable moiety and a nucleic acid, wherein said gene delivery device comprising a graspable surface for attachment to a contact surface and at least one contact surface.

In the instance that claim 17 is dependent on claim 12, claim 17 is drawn to a kit according to claim 12, wherein said delivery device further comprising a longitudinal axis and said contact surface is detachable from said graspable element.

In the instance that claim 19 is dependent on claim 12, claim 19 is drawn to a kit according to claim 12, wherein said delivery device further comprising a lumen and having an opening close to said contact surface for delivering pharmaceutical composition to a tissue being contacted with said contact surface.

In the instance that claim 20 is dependent on claim 12, claim 20 is drawn to a kit according to claim 19, where in said delivery device further comprising a double barreled syringe and conduit-tubing.

Hoffeman teaches an apparatus for delivering pharmaceutical compounds and genes into live cells of a patient, wherein said apparatus comprises a contact surface (see Figure 1 and 2, part 16), and said contact surface is a sponge-like substrata (see Figure 2, part 20, page 3, column 2, line 59). Said apparatus also comprises a flexible tube coupled to the contact surface, wherein

the other end of the tube is coupled to a fluid medium source (see Figure 1, part 32 and 14), and fluid comprising pharmaceutical composition can be drawn from the medium source and deliver through the opening of the tube to said contact surface (see page 3, column 2, line 53-58). Said apparatus further comprises a handle and an arm with an attachable head (see Figure 1, part 10, 26 and 16). Although, Hoffeman does not specify what is the fluid medium source, it is reasonable to suggest that a double barreled syringe is within the spectrum of his disclosure. However, Hoffeman does not teach a kit comprising said device and a pharmaceutical composition comprising a dye or other detectable moiety and a nucleic acid.

It would have been obvious to one of the skilled in the art to include a dye or other detectable moiety in the pharmaceutical composition. The ordinary artisan would have been motivated to do so because mixing a dye or other detectable moiety with pharmaceutical composition would enable one to monitor whether the composition has reached the desired tissue site. The ordinary artisan would have a reasonable expectation of success because mixing a dye in the pharmaceutical composition is a routine practice. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 2, 3, 13, 15, 16, 18 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J Clark can be reached on 703-305-4051. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
December 31, 2001

REMY YUCEL, PH.D
PRIMARY EXAMINER